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- 22. The method of claim 14, wherein the animal is man.
- 23. The method of claim 15, wherein the animal is man.
- 24. The method of claim 16, wherein the animal is man.
- 25. The method of claim 17, wherein the animal is man. -

REMARKS

Applicants have amended the claims in order to more particularly define the invention taking into consideration the outstanding Official Action.

The claim objection has been obviated by the deletion of the parenthetical expression from the claims and therefore it is most respectfully requested that this objection be withdrawn.

The rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite has been carefully considered but is most respectfully traversed in view of the amendments to the claims. This is similarly true with respect to claims 1-6 which have been rejected under 35 U.S.C. 101.

More particularly, all the claims have been canceled from the application and a new set of claims has been added. The claims now in the application are claims 10-25. Claim 10 is the new main method claim which provides for regulating the flux of a fluid and electrolytes in the intestine of an animal so that 1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins which comprises feeding the animal a sufficient quantity of foodstuff prepared from cereals having enzymatic activity. Thus,

the present claims clearly define the invention in terms of the necessary method steps thereby obviating this aspect of the rejection under 35 U.S.C. 112 and 35 U.S.C. 101.

The "including man" language has not been included in claim 10 and a separate set of claims as been added directed to this aspect of the invention. Obviously man in the generic sense, which includes men, women children and infants, is used in the claim which is not restricted to man per se. Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The rejections of claims 1-6 under 35 U.S.C. 112 and of claims 1-6 under 35 U.S.C. 101 have been obviated by the amendments to the claims. Accordingly, it is most respectfully requested that these rejections be withdrawn.

The rejection of claims 1-9 under 35 U.S.C. 103 as being unpatentable over Bolles et al. and Camburn in view of Witt et al. has been carefully considered but is most respectfully traversed. Each of the points raised by the Examiner in paragraphs 7, 8, 9 and 10 has been carefully considered but Applicants do not agree that the presently claimed invention is prima facie obvious taking into consideration the level of skill of one of ordinary skill in the art to which the invention pertains. The standard of obviousness is that the prior art must provide the necessary motivation to combine the references and arrive at the claimed invention. This motivation may not be provided by Applicants' specification as this would result in impermissible hindsight. Obvious to try is not the standard of obviousness under 35 U.S.C. 103.

More particularly, U.S. 5,296,243 being the inventors' own publication is acknowledged as prior art in the paragraph bridging pages 1 and 2 of the present application. The comments in therein should be noted. This prior art relates to a process for correcting and optimizing the composition of a feed for regulating the exchange of fluid and electrolytes in the gut of animals by adding certain sugars and

amino acids to the feed. The objective is achieved by the fact that the addition to the feed of certain sugars and amino acids induces formation of antisecretory proteins named "feed-induced lectines" (FIL) in this patent.

The object of the present invention is to provide a foodstuff alleviating or remedying the problems and phenomena associated with undesired secretion of body fluids, and this is accomplished, according to the presently claimed invention, by regulating the net flux of fluid and electrolytes in the intestine by the addition of enzymes.

The regulation of the flux of fluid and electrolytes is achieved, according to the present invention, by using products for the preparation of foodstuff having such an enzymatic activity that the foodstuff, when consumed, induces antisecretory proteins (ASP). According to the claimed invention it has been shown that the ASP level required in order to obtain the intended effect is at least 0.5 units of ASP per ml of blood. Any product having enzymatic activity to induce the desired formation of ASP can be used. One of ordinary skill in the art to which the invention pertains, can easily, by routine tests, measure the response to the ASP induction of the foodstuff according to the method stated in U.S. 5,296,243. Briefly, the method involves measuring a standardized secretion response in the small intestine of a rat (cf. also Example 1 of the present application). It is obvious that foodstuffs prepared according to the invention can be varied in a great number of ways and be given by different embodiments. Owing to this, diet monotony can be avoided. The need of stimulation of different individuals to reach an effective ASP concentration can be met by measuring the response of food intake, as stated above. Through the invention, one can also compensate for varying activity of enzyme preparations as well as for differences in enzymatic activity between e.g. malted cereals.

It is to be noted that U.S. 5,296,243 does not disclose or even indicate the control of the amount of formed antisecretory proteins by the use of products having

enzymatic activity in the preparation of foodstuff. As is also evident from the International Preliminary Examination Report, the Examiner of the PCT authority considered all claims new and inventive over the prior art with respect to the corresponding PCT application.

The use of foodstuff prepared from cereals having enzymatic activity does not require any special permit or acceptance from food inspection authorities. This is one advantage of the invention. Further, the desired effect, induction of antisecretory proteins, is safely and reproducibly achieved. The method for measuring this effect is described in the specification and suitable limits to be achieved are given. The invention enables the user of the invention to produce tasty and varying foods which provide the objective of the invention.

The known use (cf. U.S. 5,296,243) of certain sugars and amino acids for achieving indication of antisecretory factor (protein) is in some instances impracticable. Some good inducing amino acids are not allowed as food supplement. The use of sugars and amino acids in prepared (baked, fried etc.) foods can reduce the activity of the prepared food by the formation of so-called Maillard compounds during cooking. The use of sugars can in some instances render the food an excessive unpleasant sweet taste. The invention solves this problem. The patents referred to by the Examiner have the purposes of reducing viscosity, solubilizing alpha-glucans or producing high fiber products and the like. None of the references cited discloses or even indicates the claimed method for regulating the flux of fluid and electrolytes in the intestine of an animal by feeding the animal a sufficient quantity of foodstuff prepared from cereals having enzymatic activity to achieve the goal that 1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins.

It is acknowledged in the Official Action that the primary references do not teach expressly to make a product that when consumed, induces antisecretory proteins regulating the flux of fluids and electrolytes in the intestines so that 1 ml of blood will

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contain at least 0.5 units of ASP. However, this is a claim limitation which is required by the claims and contrary to the assertion in the Official Action, the amount of feed will be sufficient so that 1 ml of blood of the animal will contain at least 0.5 units of antisecretory proteins and this could be readily determined by one of ordinary skill in the art to which the invention pertains without undue experimentation. In view of the clear failure of the prior art to suggest the essence of the invention, it is most respectfully requested that the rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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